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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,785	03/17/2000	Oleg N. Suslov	4350.001200	3947

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/527,785

Applicant(s)

Suslov et al

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/23/01 and 3/13/02
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5 and 12-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5 and 12-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3-4 6) ☐ Other:

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DETAILED ACTION

1. Applicant's election of Group II (claims 2-5 & 15-21) in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that claims 12-14 were not included in an appropriate group in Paper No. 7. These claims are therefore included in elected Group II.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-5 & 12-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In other words, patents are granted only for "any new and useful *process, machine, manufacture, or composition of matter*". In contrast, the claimed *idea* of a "spectrum" or "profile" is not a patentable invention. See MPEP 706.03(a).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-5 & 12-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification lists cDNA clones isolated from neurospheres in Tables 3-5. However, as illustrated in Table 5 and pages 49-50, not a single cDNA clone that comprises a complete open reading frame is disclosed. Nor is a complete "temporal gene transcript spectrum" described, nor are any "collection of gene transcripts" described, nor are any "plurality of ... clones "characterized" by which one of ordinary skill in the art could visualize what nucleotide sequences comprise such "temporal gene transcript spectrums", "temporal neuromorphogenesis profiles", or "collection of gene transcripts", as claimed. Moreover, although murine and human neurospheres are described for use in obtaining a "temporal gene transcript spectrum", etc. only one human and one murine sequence is described on pages 49-50 in which no written description of any other sequences nor sequences from any different species are provided within the instant specification. Additionally, no written description is provided as to what structurally constitutes nucleotide sequences comprising unknown and undescribed promoter sequences, 5'- or 3'- flanking or enhancer regions, introns, allelic variants, or other sequences comprising any "gene" sequence, in that no sequences for these different molecules are described; nor can they be visualized by one skilled in the art. Therefore, one skilled in the art cannot reasonably visualize

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or predict what critical nucleic acid residues would structurally characterize the genus of “temporal gene transcript spectrums”, “temporal neuromorphogenesis profiles” or “collection of gene transcripts”, etc.; or what sequences would comprise such. Thus, the written description requirements under 35 U.S.C. 112, first paragraph are not met.

Applicant is directed toward the Revised Interim Utility and Written Description Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999.

4. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This claim is dependent on cancelled base claim 1.

5. Claims 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, these claims lack antecedent basis to base claim 12, because claim 12 is not directed toward a “profile” (i.e., as it relates to claims 13 & 15-18) or a “method” (i.e., as it relates to claim 14).

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6. Claims 2-5 & 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: 1) how analyzing for “phenotype markers” is accomplished, 2) “subtractively comparing [what] selected pair of amplified cDNA libraries”, 3) how and when “constructing a temporal spectrum...” is accomplished (i.e., as it relates to nonelected base claim 1). How and when “a plurality of... clones” are “characterized” (i.e., as it relates to claim 3). What an “iterative arrangement of clones” entail, or when such is accomplished (i.e., as it relates to claim 17).

7. Claims 2-3, 5 & 12-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what exactly is being claimed, in that the metes and bounds of an unidentified “at least one developmental phenotype cell marker” or an unidentified “amount of expressed phenotype cell marker” are unknown; especially when none are recited (i.e., as it relates to claims 3 & 3). It is unclear what metes and bounds “a temporal array of pluripotent neural stem/ progenitor cell developmental gene transcripts” entail or what “*different* second selected cells” entail or what “*identified* developmental stages of neurogenesis” entail or what “phenotypic neural cell development” is envisioned to be “correlate[d]” with; especially when none are recited (i.e., as it relates to claims 12 & 17). Moreover, it is unclear what metes and

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bounds "*housekeeping, phenotypic and developmental gene transcripts*" entail so that a "distinct[ion]" can be assessed in that no such transcripts are adequately defined in the specification nor completely recited in the claims (i.e., as it relates to claims 19-21).

8. Claims 2-5 & 12-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is ambiguous what exactly is being claimed, in that neural stem cells and progenitor cells are distinct types of cells at different stages of development; thereby, making the additional requirement of these cells being "pluripotent" further confusing and contradictory. Note that the term "pluripotent" is art recognized as giving rise to any cell type, such as that expected during the initial stages of embryogenesis. Therefore, the term "multipotent" may be more appropriate when referring to neural stem cells, if proper basis exists in the specification. In contrast, neural progenitor cells can be either neuronal progenitor or glial progenitor cells depending on their differentiation commitment. Clarification or amendment of the claims, therefore, is required.

Claim Rejections - 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-5 & 12-21 are rejected under 35 U.S.C. 102(a) as being anticipated by
Cytotherapeutics, Inc (WO 99/11758; Suppl. IDS Ref #B1).

Cytotherapeutics disclose isolation of neural stem cells and making cDNA libraries from such (i.e., as it relates to a "temporal gene transcript neurogenic spectrum/neuromorphogenesis profile"; pg. 27; as it relates to claims 2-3). In that Cytotherapeutics teach isolation of neurospheres (e.g., pg. 14) which reasonably comprise type I, II or III stem cell, the limitation of claims 5 & 12-16 are met. In that developmental phenotype cell markers, or any other gene transcript inherently expressed in these cells comprise the temporal gene transcript neurogenic spectrum/neuromorphogenesis profile or "collection of gene transcripts" within Cytotherapeutics' cDNA library, the limitations of claims 4 & 17-21 are also anticipated; absent evidence to the contrary.

10. Claims 2-5 & 12-21 are rejected under 35 U.S.C. 102(b) as being anticipated by
Arsenijevic et al. (Suppl. IDS Ref #C1).

Arsenijevic et al. disclose isolation of total RNA from neurospheres comprising stem and progenitor cells by reverse transcribing them using PCR to make a temporal gene transcript neurogenic spectrum/neuromorphogenesis profile (e.g., pg. 2119-2120; as it relates to

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claims 2-3). In that Arsenijevic et al. teach isolation of neurospheres (e.g., pg. 2118-2119) which reasonably comprise type I, II or III stem cell, the limitation of claims 5 & 12-16 are met. In that β -actin cDNA is further isolated by Arsenijevic, the limitations of claims 4, 17 & 20 are met. In that developmental phenotype cell markers (e.g., IGF receptor), or any other gene transcript inherently expressed in these cells comprise the temporal gene transcript neurogenic spectrum/neuromorphogenesis profile or "collection of gene transcripts" contained in the initial total RNA of Arsenijevic, the limitations of claims 4 & 17-21 are also anticipated; absent evidence to the contrary.

11. Claims 2-5 & 12-21 are rejected under 35 U.S.C. 102(b) as being anticipated by De Adams et al. (IDS Ref #C1).

Adams et al. disclose isolation of total RNA from a whole post-natal female human brain, which comprises neural stem and progenitor cells (e.g., pg. 380). Adams disclose using PCR to make clones from poly(a) RNA; thereby, generating a "temporal gene transcript neurogenic spectrum/neuromorphogenesis profile" (i.e., as it relates to claims 2-3). In that Adams' PCR-generated cDNA libraries reasonably were generated from poly(A) RNA from type I, II and/or III stem cells, and comprises developmental phenotype cell markers, as well as any other gene transcript inherently expressed in these cells from a juvenile human brain, the limitations of claims 4-5 & 12-21 are anticipated; absent evidence to the contrary.

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Conclusion


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
June 6, 2002


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